



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/781,579	01/09/97	GARDINER	B GONR9003HED/

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QM31/1112

EXAMINER

PHAM, T

ART UNIT

PAPER NUMBER

3731

DATE MAILED:

11/12/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/781,579

Applicant(s)
Gardiner et al.

Examiner
Tina Pham

Group Art Unit
3731



☒ Responsive to communication(s) filed on Aug 24, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-16, 18, 19, 21-23, 26-31, and 36-55 is/are pending in the application

Of the above, claim(s) 37-42 and 50-55 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-16, 18, 19, 21-23, 26-31, 36, and 43-49 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8 & 10

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

Applicant's election of Group I in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election with traverse of Species 1, claims 1-16, 18, 19, 21-23, 26-31, 36, 43-49, in Paper No. 11, dated Aug 24 1998, is acknowledged. The traversal is on the grounds that the species are not patentably distinct and that there is no burdensome search on the Examiner. This is not found persuasive because although the search is similar, it does diverge when the specifics of each species are involved.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 26-31, 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Barrows et al. in Patent 4,719,917.

Note figure 3, a surgical fastener comprises a base (6) having at least one substantially planar surface, a flange (8) is bendably joined to a first edge of the base, a pin (8) is bendably joined to the base at a second edge of said base opposing the first edge, a needle (4) is removably joined to the pin (8), said base (6) is configured to be releasably engaged with an associated instrument.

With respect to claims 26-28, 31, pin (8) is a first section, base (6) is a second section, flange (8) is a third section, and needle (4) is a piercing implement.

Claims 5-8, 10, 12-15, 19, 21-23, 43-45, 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by McGarry et al. in Patent 5,366,479.

Note all figures, an instrument for applying a surgical staple comprises of: an elongated shaft (14) having a distal end portion; a staple holder (16) at the distal end portion, a staple forming member (104) at the distal end portion (col. 19, lines 41-53); a handle having a control for actuating the staple forming member; said staple holder (16) can articulate and the handle has a control for actuating an articulating mechanism.

With respect to claim 5, the staple and the needle are set forth in the functional language, not as a definite part of the invention. The functional language drawn to intended use, “ adapted

to engage a staple and a needle . . . the base opposing said first edge” cannot serve to distinguish over the prior art which includes all of the structural elements called for in the claims and can thus inherently perform in the same manner as the claim invention.

Similarly, with respect to claim 12, the recitation “for holding a staple . . . a graft to an artery” is a functional statement. Therefore, it is given minimal patentable weight.

McGarry also discloses a method comprises the steps of: providing an instrument as described above; providing a staple holder (16) with at least one staple (see figure 28) comprises a base (110c), a flange (110BR), a pin (110BL), a needle (110L); incising a patient’s tissue to create at least one opening; inserting the distal end of the instrument through the opening, so that the distal end is disposed in the patient, passing the needle (110L) through a portion of one tissue; actuating the staple forming member.

With regard to claim 43, member (110c) is the first section, member (110R) is the second section, member (110L) is the needle.

Claims 5, 9, 12, 16, 43-46 are rejected under 35 U.S.C. 102(b) as being anticipated by European Patent 129,441 (‘441).

Note all figure, Patent ‘441 discloses an instrument (100) for applying a surgical staple comprises of: an elongated shaft (106); a staple holder (101); a staple forming member; a handle (110); a needle removing member (160); means for articulating the staple (108); a staple (60) including a first section and a second section, a needle (70) is affixed to the staple.

With respect to claim 5, the staple and the needle are set forth in the functional language, not as a definite part of the invention. The functional language drawn to intended use, “ adapted to engage a staple and a needle . . . the base opposing said first edge” cannot serve to distinguish over the prior art which includes all of the structural elements called for in the claims and can thus inherently perform in the same manner as the claim invention.

Similarly, with respect to claim 12, the recitation “for holding a staple . . . a graft to an artery” is a functional statement. Therefore, it is given minimal patentable weight.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

Claims 11 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGarry et al. in Patent 5,366,479.

McGarry discloses the invention as described above. However, McGarry does not disclose the claimed dimensions. It would have been an obvious matter of design choice to design the device to have the claimed dimensions, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

The question under section 103 is whether the subject matter as a whole would have been obvious, not whether the differences would have been obvious. *In re McLaughlin*, 170 USPQ 209 (CCPA 971); and *In re Etter*, 225 USPQ 1 (Fed. Cir. 1985).

Change in dimension, degree, size, ect. without special functional significance are not patentable. *Research Corp. v. Nasco Industries, Inc.*, 501 F2d 358; 182 USPQ 449 (CA 7), cert. denied 184 USPQ 193; USLW 3359 (1974), *In re Rose*, 105 USPQ 137, and *In re Aller et al.*, 105 USPQ 233.

Conclusion

Any inquiry concerning this communication or earlier communications should be directed to Tina D. Pham at telephone number (703) 308-0824. The examiner can normally be reached Monday through Friday from 7:30 AM to 4:00 PM.

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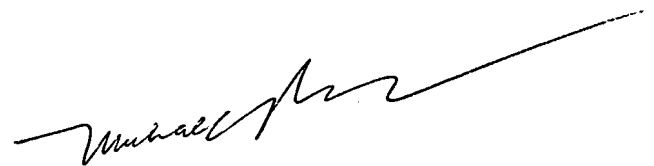
Paper No. 12

If an inordinate number of attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Michael Buiz can be reached at (703) 308-0871. The fax number for the Art Unit is (703) 308-0758.

Any inquiry of a general nature or relating to the status of the application should be directed to the Group receptionist at (703) 308-0858.

Tina T. D. Pham

November 08, 1998


MICHAEL BUIZ
SUPERVISORY PATENT EXAMINER
GROUP 3300
11/8/98